

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: PALBOCICLIB PATENT
LITIGATION

)
) MDL No. 19-2912 (CFC)
)
)

PFIZER INC., WARNER-LAMBERT
COMPANY LLC, PF PRISM C.V., PFIZER
MANUFACTURING HOLDINGS LLC,
PFIZER PFE IRELAND
PHARMACEUTICALS HOLDING 1 B.V.,
and PF PRISM IMB B.V.

Plaintiffs,

v.

)
) C.A. No. 19-743 (CFC) (Consolidated)
)
)

AIZANT DRUG RESEARCH SOLUTIONS
PVT. LTD.,

Defendant.

PFIZER INC., WARNER-LAMBERT
COMPANY LLC, PF PRISM C.V., PFIZER
MANUFACTURING HOLDINGS LLC,
PFIZER PFE IRELAND
PHARMACEUTICALS HOLDING 1 B.V.,
and PF PRISM IMB B.V.,

Plaintiffs,

v.

)
) C.A. No. 19-1863 (CFC)
)
)

MYLAN PHARMACEUTICALS, INC.

Defendant

STIPULATED PROTECTIVE ORDER

Disclosure and discovery in the above-caption matters (“Actions”) may involve the production of certain confidential, proprietary, or private documents, things, and information (including electronically stored information) in the possession, custody, or control of a party or a non-party that constitute or contain trade secrets or other confidential research, development, manufacture, regulatory, financial, marketing, or other competitive information within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure or contain information involving privacy interests of individuals for which special protection from public disclosure and from use for any purpose other than prosecuting and defending the Actions may be warranted. Accordingly, Plaintiffs Pfizer Inc.; Warner-Lambert Company LLC; PF PRISM C.V.; Pfizer Manufacturing Holdings LLC; Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.; and PF PRISM IMB B.V. (collectively, “Plaintiffs” or “Pfizer”) and Defendants Aizant Drug Research Solutions Pvt. Ltd. (“Aizant”); Alembic Pharmaceuticals, Inc. and Alembic Pharmaceuticals Ltd. (collectively, “Alembic”); Apotex, Inc. and Apotex Corp. (collectively, “Apotex”); Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialties Ltd. (collectively, “Aurobindo”); Cipla USA Inc. and Cipla, Ltd. (collectively, “Cipla”); Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, “DRL”); Hetero USA Inc., Hetero Drugs, Ltd., Hetero Labs, Ltd. Unit-V, and Hetero Labs, Ltd. (collectively, “Hetero”); Mylan Pharmaceuticals Inc. (“Mylan”); Natco Pharma Inc. and Natco Pharma, Ltd. (collectively, “Natco”); Qilu Pharma, Inc. and Qilu Pharmaceutical Co., Ltd. (collectively, “Qilu”); Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE (collectively, “Sun”); Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited (collectively, “Teva”); and Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide

DMCC, and Cadila Healthcare Ltd. (collectively, “Zydus”) have in good faith conferred and hereby stipulate to the entry of the following Protective Order in the Actions:

1. **Scope of Protective Order.** This Protective Order shall apply to all information, documents and things produced or within the scope of discovery in these Actions, including, without limitation, all testimony adduced at depositions, documents or things produced in response to requests for the production of documents and things, answers to interrogatories, responses to requests for admission and all other discovery taken pursuant to the Federal Rules of Civil Procedure, as well as hearing or trial transcripts, matters in evidence, and any other information furnished, directly or indirectly, by or on behalf of any party to this Action or any Third Party to the extent such material is designated “Confidential Information” in accordance with ¶ 2 of this Protective Order. This Protective Order shall also govern any designated record of information produced in these Actions pursuant to required disclosures under any procedural rule or District of Delaware Local Rule, and any supplementary disclosures thereto.

2. **Definitions.**

a. “Producing Party” means a party or Third Party producing Confidential Information under this Protective Order.

b. “Receiving Party” means a party or Third Party receiving Confidential Information under this Protective Order.

c. “Confidential Information” means all information, in any form, that constitutes a “trade secret or other confidential research, development or commercial information” within the meaning of Fed. R. Civ. P. 26(c)(1) and includes, without limitation, all information that is not generally known to public or to competitors and that relates to product research, product development, product manufacturing, financial performance (whether

historical or future), marketing, sources of supply, business relationship with third parties, market analysis, or strategic planning.

d. “Third Party” or “Third Parties” means any person or entity who is not a named party in these Actions.

3. **Third Parties Under the Protective Order.** If a Third Party provides discovery to any party in connection with these Actions, and if the Third Party so elects, then the provisions of this Protective Order shall apply to such discovery, and the parties will treat all information that is produced by such Third Party in accordance with the terms of this Protective Order to the extent it is designated as Confidential. Under such circumstances, the Third Party shall have the same rights and obligations under this Protective Order as held by the parties to these Actions. Because Third Parties may be requested to produce documents containing information that a party considers Confidential Information, at the request of any party all documents produced by a Third Party in this action shall be treated as if designated Confidential hereunder for a period of seven days after production in order to allow the parties time to review the documents and make any appropriate designations hereunder.

4. **Designation.** Each party shall have the right to designate as “Confidential” any information that is Confidential Information as defined in paragraph 2(c), in accordance with the terms of this Protective Order. The designation of information as “Confidential” by the Producing Party constitutes a representation of that party that it reasonably and in good faith believes that the designated material constitutes Confidential Information. To the extent that material is designated Confidential, such material shall only be revealed to or used by limited categories of individuals, as provided for herein, and shall not be communicated in any manner, either directly or indirectly, to any person or entity except as provided herein. Any copies of

such material, abstracts, summaries, or information derived therefrom, and any notes or other records regarding the contents thereof, shall also be deemed Confidential, and the same terms regarding confidentiality of these materials shall apply as apply to the originals. The procedures for designating materials as Confidential are as follows:

a. **Designation of Documents and Things.** The parties and any Third Parties may designate as “Confidential” a document or thing that constitutes or contains Confidential Information by labeling or marking each page of that document with the legend “**CONFIDENTIAL**,” or by otherwise marking or designating in writing the materials as Confidential and subject to the Protective Order at the time such document or thing is produced to the Receiving Party. Anything that cannot be so marked shall be designated Confidential by placing the appropriate legend on a container or package in which the thing is produced or on a tag attached thereto. Each page of each document and each thing produced pursuant to discovery in this Action shall also bear a unique identifying number.

Documents and things produced without a legend designating the material Confidential shall not be subject to this Protective Order unless otherwise agreed by the parties, ordered by the Court, or designated Confidential in accordance with the provision of paragraph 9 of this Protective Order (addressing inadvertent production). Inspection of documents or things by any party shall be conducted only by persons eligible to receive Confidential Information under this Protective Order. Such persons shall treat all information obtained during or from any inspection as though it were designated Confidential until such time as copies of documents or things from the inspection are produced, and, thereafter, such produced documents and things shall be treated in accordance with any confidentiality designation appearing on the document or thing at the time of its production.

A Producing Party may redact Confidential Information in a document or thing if that information is not relevant to the subject of this litigation or is subject to the attorney-client privilege or attorney work product protections. Any such redaction, regardless of size, shall be clearly labeled. This paragraph shall not be construed as a waiver of any party's right to seek disclosure of redacted information, in accordance with paragraph 26 below. All documents redacted based on attorney-client privilege or work-product immunity shall be listed on a privilege log in accordance with Federal Rule of Civil Procedure 26(b)(5) and exchanged at a mutually agreeable date and time.

b. **Designation of Interrogatories, Requests for Admission and Written Testimony.** Any response to written interrogatories or requests for admission, or any testimony adduced at a deposition upon written questions (or any portion of any of the foregoing) that constitutes or contains Confidential Information, may be designated "Confidential" by the party providing the response or testimony as follows: (i) the specific pages or portions of pages containing Confidential Information shall be marked with the legend "**CONFIDENTIAL**", and (ii) the first page of that document near the caption shall be marked with the legend "**CONFIDENTIAL.**" Responses or testimony served without these legends shall not be treated as Confidential subject to this Protective Order unless otherwise agreed by the parties or ordered by the Court, or designated Confidential in accordance with the provisions of paragraph 9 of this Protective Order (addressing inadvertent production).

c. **Designation of Deposition Transcripts.** Deposition transcripts containing Confidential Information may be designated Confidential in accordance with this Protective Order either (1) on the record during the deposition, or (2) by providing written notice within 60 days of the date on which the deposition occurred.

All deposition transcripts not previously designated Confidential during the deposition shall be treated as Confidential under this Order for a period of 60 days from the date on which the deposition occurred, unless otherwise agreed to by the parties. After 60 days, deposition transcripts shall no longer be treated as Confidential unless one of the parties participating in the deposition has designated all or a portion of the testimony Confidential, or as otherwise agreed to by the parties. The parties agree to mark at least the first page of all copies of deposition transcripts that contain testimony, or that append exhibits, designated as Confidential with the legend “**CONFIDENTIAL**,” and to provide each other notice of which portions of the deposition transcript contain Confidential Information. This paragraph does not limit any party’s right to challenge any presumptive designation or preclude a Producing Party from designating testimony or transcripts as Confidential Information.

d. **Designation of Hearing Testimony or Argument.** With respect to testimony elicited during hearings and other proceedings, whenever counsel for any party deems that any question or line of questioning calls for the disclosure of Confidential Information, counsel may designate on the record prior to such disclosure that the disclosure shall be deemed Confidential under the terms of this Protective Order. Whenever matter designated Confidential is to be discussed in a hearing or other proceeding, any party claiming such confidentiality may ask the Court to have excluded from the hearing or other proceeding any person who is not entitled under this Order to receive information so designated.

5. **Limitations on Attendance at Depositions.** Counsel for a Producing Party may request that all persons other than those individuals expressly permitted access to Confidential Information under this Protective Order leave the deposition room during the portion of the deposition that inquires about or discloses subject matter that counsel for the Producing Party

believes to constitute Confidential Information. If individuals other than those specified in the previous sentence fail to leave the deposition room during any portion of the deposition that inquires about or discloses what counsel for the Producing Party believes to constitute Confidential Information, counsel for the Producing Party may seek relief from the appropriate Court and, pending resolution of its request for relief, instruct the witness not to answer questions relating to, or limit disclosure of, the Confidential Information at issue.

6. **Limitations on Attendance at Hearings or Trial.** Counsel shall confer with each other and with the Court regarding procedures to protect the confidentiality of any material marked, labeled, or otherwise designated Confidential that a party or any of its witnesses may use, refer to, disclose, or admit into evidence during trial or any hearing in this Action. Unless the Court orders otherwise, attendance at a hearing or at a trial session in this Action at which material designated Confidential will be used or disclosed shall be limited for the time period during which Confidential Information will be used or disclosed to individuals entitled to have access to such materials under the terms of this Protective Order.

7. **Use and Disclosure of Designated Information.** Subject to the limitations and restrictions of this Protective Order and any further order regarding confidentiality that the Court may enter, material marked, labeled, or otherwise designated Confidential as described in this Protective Order may be used to prepare for and conduct discovery, to prepare for trial, and to support or oppose any motion or other filing in these Actions, and may be used in testimony at trial, offered into evidence at trial and/or hearings on motions subject to such procedures mandated by the Court. Nothing herein shall be construed to affect in any way the admissibility of any document, testimony or other evidence at trial.

Material designated Confidential, and all information derived therefrom, shall be used only by persons permitted access to such information under this Protective Order, shall not be disclosed by the Receiving Parties to any party or person not entitled under this Protective Order to have access to such material, and shall not be used by the Receiving Parties for any purpose other than in connection with these Actions, including without limitation for any research, development, manufacture, patent prosecution, financial, commercial, marketing, regulatory, business, or other competitive purpose (except for settlement of the above-captioned case). Absent written consent of the Producing Parties or further order of this Court, all persons receiving information designated Confidential are expressly prohibited from using or disclosing such information in connection with any practice before or communication with the United States Patent and Trademark Office or the Patent Trial and Appeal Board, with the FDA (including Citizen Petitions), the United States Pharmacopoeia, or their counterpart organizations in any foreign jurisdiction, and are expressly prohibited from disclosing such information in connection with any civil action other than the above-captioned Actions.

8. **Storage of Designated Information.** The recipient of any information designated as Confidential shall maintain such information in a secure and safe area and shall exercise the same standard of due and proper care with respect to the storage, custody, use and/or dissemination of such information as is exercised by the recipient with respect to his/her/its own proprietary information.

9. **Inadvertent Production of Confidential Information.** If a party inadvertently produces or provides discovery of any Confidential Information without labeling or marking it as provided in this Protective Order, the Producing Party may give written notice to the Receiving Party or parties, within ten business days after becoming aware of the inadvertent production,

that the information should be treated as Confidential in accordance with the provisions of this Protective Order. The Producing Party will provide copies of the properly marked information (e.g., documents, discovery responses, transcripts, things, and/or all other information within the scope of this Protective Order). Upon receipt of such notice and properly marked information, the Receiving Party or parties shall return or destroy said unmarked or incorrectly marked information to the extent practicable and not retain copies thereof, and shall undertake a best effort to correct any disclosure of such information contrary to the redesignation. Prior to receipt of such notice, disclosure of such documents, things, information, responses and testimony to persons not authorized to receive Confidential Information shall not be deemed a violation of this Protective Order.

10. **Limitations on Advice to Clients.** It is understood that counsel for a party may give advice and opinions to his or her client based on his or her evaluation of designated Confidential Information received by the party, provided that such rendering of advice and opinions shall not reveal the content of Confidential information, other than in summary form, except by prior written agreement with counsel for the Producing Party or as otherwise set forth in this Protective Order.

11. **Inadvertent Production of Privileged or Work Product Information.** Notwithstanding anything to the contrary in Fed. R. Civ. P. 26(b)(5)(B) or in any other provision of this Protective Order, the inadvertent production or disclosure of any document or tangible thing (including information) that is subject to a claim of attorney-client privilege or work-product immunity, or other privilege or immunity, shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claims of attorney-client privilege, work-product immunity, or other privilege or immunity. In such an event, the Producing Party shall send to

each Receiving Party a written request for return of the inadvertently produced or disclosed document or thing within a reasonably prompt period of time after becoming aware of such inadvertent or mistaken production. Within five business days of receiving a written request to do so from the Producing Party, the Receiving Party shall (a) return to the Producing Party any documents or tangible items that the Producing Party represents are covered by a claim of attorney-client privilege or work-product immunity, or other privilege or immunity, and were inadvertently or mistakenly produced and (b) destroy any copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information, including any electronic records thereof. The Receiving Party shall not utilize the information contained in the inadvertently produced documents or things for any purpose, or disseminate or transmit such information, after receiving written notice that it is subject to a claim of attorney-client privilege or work-product immunity.

12. If the Receiving Party wishes to contest that any such document or thing is protected from disclosure by the attorney-client privilege, work product immunity or other privilege or immunity from discovery, it shall so notify the Producing Party in writing when the document or thing is returned to the Producing Party (“Notice of Designation”).

13. Within five days after receiving a Notice of Designation, the Producing Party shall provide to the Receiving Party for each document or thing a description of the basis for the claim of privilege or immunity.

14. Within five days after receiving such description, the Receiving Party may seek relief from the Court to compel production of such documents and things, the protection of which is still disputed, in accordance with the procedures set forth in the Court’s Scheduling

Order for resolution of discovery disputes. The party claiming the privilege or immunity shall have the burden of proving that such privilege or immunity exists.

15. With respect to documents and things subsequently generated by a Receiving Party, which documents and things contain information derived from such inadvertently produced documents and things, if the Receiving Party does not notify the Producing Party that the Receiving Party disputes the claims of attorney-client privilege or work-product immunity, or if the Court rejects any challenge by the Receiving Party to the privileged status of the inadvertent production, the Receiving Party shall either destroy the derivative documents and things or redact from them all such derivative privilege or work-product information in a manner such that the derivative information cannot in any way be retrieved or reproduced.

16. If, in a deposition, hearing, or other proceeding the party who made the inadvertent production or disclosure makes a request on or off the record for return of the inadvertently produced or disclosed document or thing within a reasonably prompt period of time after recognizing that the information has been produced or disclosed, all copies of the inadvertently produced or disclosed document or thing present at the deposition, hearing, or other proceeding shall immediately be sequestered and there shall be no further use of the inadvertently produced or disclosed document or thing. For the avoidance of any dispute, the marking of an inadvertently produced or disclosed document or thing as an exhibit at deposition, hearing, or other proceeding has no bearing on the timeliness of the request for return.

17. The procedures set forth in this paragraphs 12–16 for challenging the privileged status of an inadvertent production shall not result in any waiver of the attorney-client privilege, the work product immunity, or any other privilege or immunity.

18. **Access to and Disclosure of Confidential Information.** Every person to whom Confidential Information is to be disclosed, summarized, described, characterized, or otherwise communicated or made available in whole or in part shall first be advised that the material or information is being disclosed pursuant to the terms of this Protective Order and provided a copy of this Protective Order. Access to and disclosure of material marked, labeled, or otherwise designated Confidential as described in this Protective Order shall be made only to the following individuals:

a. Outside trial counsel or outside attorneys of record for the parties, including, but not limited to, such attorneys' partners, associates, staff and contract attorneys, and their authorized secretarial, paralegal, clerical, and legal-assistant staff whose duties and responsibilities require access to material designated Confidential.

b. Three in-house legal or intellectual property personnel for each party, or any parent or subsidiary entity of each party, as identified in Exhibit B,¹ who are actively responsible for either (a) directing the management and conduct of these Actions or (b) providing a party with legal advice with respect to these Actions, provided that the in-house designee first agree to be bound by the terms of this Protective Order by executing a copy of the attached Exhibit A. A party designating an individual under this paragraph represents that such designees do not, and will not for a period of one year following the final disposition of these Actions, have competitive decision-making authority for product marketing or business strategy (such as pricing and product design) relating to Ibrance® or any product containing palbociclib as its active ingredient. Notwithstanding the foregoing provisions, in-house designees shall be

¹ Exhibit B will be submitted within three business days after the day on which this Protective Order is entered by the Court.

permitted to advise their clients regarding legal strategy and the pending Actions; provided, however, that Confidential Information is not thereby disclosed.

c. Outside consultants or experts and their staffs retained by the parties or their attorneys for purposes of this action, who first agree to be bound by the terms of this Protective Order by executing a copy of the attached Exhibit A, in accordance with paragraph 19, and who are not objected to pursuant to paragraph 20.

d. The Court before which these Actions are pending and their authorized staff.

e. Court reporters, videographers, and their respective staffs employed in connection with this action.

f. Any interpreter or translation service retained to assist outside counsel of record, and any typist or transcriber used thereby, who either first executes a copy of the Confidentiality Undertaking attached as Exhibit A or has made suitable arrangements with the party that has retained such an individual to preserve the confidentiality of the Confidential Information.

g. Non-parties specifically retained to assist outside counsel of record with copying and computer services necessary for document handling, other litigation support personnel (e.g., graphic designers and animators, database entry personnel), and other third-party vendors, subject to the limitations of paragraph 21; and

h. Any other person as to whom the parties agree in writing.

No party shall disclose any material designated Confidential by a Producing Party to another party without the consent of the Producing Party or by order of the Court, provided however, that any party shall be permitted to disclose in any trial, hearing, pleading, discovery

response, deposition, or expert report that is properly designated as “Confidential” pursuant to this Order any material designated Confidential by any Producing Party. Notwithstanding anything in the paragraph, no party shall disclose to a fact witness of one party, during his or her deposition, any material designated Confidential by another party.

The individuals specified in paragraphs 18(a) – 18(b) who have received access to information designated Confidential by any party other than his or her client/employer shall not thereafter prosecute, supervise, or materially assist in the prosecution of any patent application (including both foreign and U.S.) that covers palbociclib (including without limitation compositions, methods, distribution methods, uses, or processes) for the length of these Actions plus 1 year after a final, non-appealable judgment in the last of these Actions to conclude. For the avoidance of doubt, “prosecution” includes directly or indirectly drafting, amending, advising, or otherwise affecting the scope of the patents-in-suit, a continuation, a divisional, a continuation-in-part, a reissue patent, or a patent application that covers palbociclib, including through the use of any post-grant proceedings such as *Inter Partes* Review, *Ex Parte* Reexamination, Covered Business Method Review, or related appeals that involve “prosecution” as set forth above. Notwithstanding the foregoing, nothing herein shall prohibit an individual from participating, supervising, or assisting with (1) the practice before or communication with the United States Patent and Trademark Office with respect to an *Inter Partes* Review, post grant review, or reissue or reexamination proceeding relating to palbociclib, or (2) pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court related to palbociclib, so long as that individual does not participate in any claim amendments. Further, such individuals specified in paragraphs 18(a) – 18(b) shall not directly participate in or advise any FDA correspondence, including Citizen Petitions, relating to pharmaceutical products

containing palbociclib for the length of this Action plus 1 year after the final, non-appealable judgment in this Action, except where such work is updating the FDA on the status of this Action, responding to an inquiry from the FDA regarding the receiving party's own NDA or ANDA at issue in these Actions, or is directed toward obtaining or maintaining approval or regulatory exclusivities of the receiving party's own NDA or ANDA at issue in these Actions, provided that such individuals shall not disclose the Confidential Information of another party in connection with such work.

19. **Identification of Experts and Consultants.** If any party desires to disclose information designated Confidential (other than its own Confidential Information) to any expert or consultant pursuant to paragraph 18 of this Protective Order, it must first identify in writing (which can be by email) to the attorneys for the Producing Party each such expert or consultant. The identification of an expert or consultant pursuant to this paragraph shall include the full name and professional address and/or affiliation of the proposed expert or consultant, an up-to-date curriculum vitae, any prior or current employments or consultancies for any party or other company in the pharmaceutical industry within the last five years that is in any way related to the research, synthesis, or development of any kinase inhibitor (except those engagements that are protected from disclosure pursuant to Fed. R. Civ. P. 26 or where the fact of the engagement itself is protected from disclosure by a confidentiality agreement), including a list of the cases in which the expert or consultant has testified at deposition, at a hearing, or at trial within the last 4 years, and an executed copy of the Confidentiality Undertaking attached hereto as Exhibit A.

20. **Objecting to Disclosure of Confidential Information to Experts and Consultants.** Counsel for the party providing discovery may, within the seven calendar day period, serve a notice of objection if a reasonable basis for such objection exists. If the notice is

served, the Confidential Information will not be disclosed to such outside consultant. Within seven calendar days after service of the objection, if the parties are unable to reach any agreement over the disclosure of Confidential Information to the expert or consultant, counsel for the objecting party may subsequently move the Court for an order denying disclosure of any Confidential Information to the outside expert or consultant as to which a notice of objection has been served, in accordance with the procedures set forth in the Court's Scheduling Order for resolution of discovery disputes. If the objecting party files this motion, the Confidential Information shall not be disclosed to the outside expert or consultant until the Court rules or the parties agree that such disclosure may be made. Failure to file such a motion within the seven calendar day period shall operate as a waiver of this objection, unless the parties agree in writing to extend this deadline while meeting and conferring regarding the objection.

21. **Third Party Vendors.** Counsel may use the services of Third Party Vendors to provide services such as document review, electronic discovery support, computerized legal support, and management services for the purpose of encoding, loading into a computer and storing and maintaining for information control and retrieval purposes, transcripts of depositions, hearing, trials, pleadings, exhibits marked by any party, briefs and accompanying affidavits and appendices, documents produced by any party, or a party's own attorney work product, all of which may contain Confidential Information. Counsel desiring to disclose Confidential Information to a Third Party Vendor for the purposes of this paragraph shall first obtain a signed Confidentiality Undertaking on the form attached as Exhibit A, from a representative of the vendor who may receive access to such material unless the Third Party Vendor is already subject to a general confidentiality obligation to such counsel. Counsel retaining the vendor shall retain

the original of each such signed Confidentiality Undertaking. Service of the Undertaking shall not be required.

a. Third Party Vendors shall return to the party's counsel or confirm destruction of all copies of transcripts or other documents containing Confidential Information within 30 days of the conclusion of the last of these Actions to conclude, including any Appeals.

22. **Disclosure to Other Individuals.** Disclosure of Confidential Information may be made to individuals not identified in paragraph 18, above, only as follows:

a. Confidential Information may be disclosed to any person not otherwise identified in paragraph 18 above as agreed in writing by the party that designated such information Confidential.

b. Any party may move the Court for an Order that a person not identified in paragraph 18 above be given access to Confidential Information after first signing an Undertaking in the form of Exhibit A attached hereto. Counsel for the moving party shall retain the original of each such signed Undertaking. Service of the Undertaking shall not be required.

c. Confidential Information of a Producing Party may also be disclosed to and/or used to examine, at deposition and at trial (or other court hearing): (i) an individual who either prepared, received or reviewed the Confidential Information prior to filing of this Action or who previously had access to or knowledge of the Confidential Information, as demonstrated on the face of the Confidential Information itself or by foundation testimony elicited during a deposition or at trial; (ii) a currently employed officer, employee or expert of a Producing Party, and/or; (iii) a witness designated for the Producing Party under Federal Rule 30(b)(6) concerning any topic to which the Confidential Information is relevant.

23. **Confidentiality of Party's Own Documents.** A party may disclose or use in any manner or for any purpose, any information or documents from that party's own files that the party itself has designated Confidential.

24. **Inadvertent Disclosure.** If Confidential Information is disclosed or comes into the possession of any person not authorized to receive such information under this Protective Order, the party responsible for the disclosure shall: (a) within five business days of becoming aware of such disclosure inform the designating party of all pertinent facts relating to such disclosure, including the identity of the person to whom the inadvertent disclosure was made; (b) use its best efforts to obtain the prompt return of the original and all copies of any such Confidential Information, and to bind such unauthorized person or party to the terms of this Protective Order; (c) within three business days of becoming aware of such disclosure, inform such unauthorized person or party of all provisions of this Protective Order; and (d) request such unauthorized person or party to sign the Confidentiality Undertaking in the form attached hereto as Exhibit A. The executed Confidentiality Undertaking shall be served upon counsel of record for the Producing Party within five business days of its execution by the person or party to whom Confidential Information was disclosed. The requirements set forth in this paragraph shall not prevent the Producing Party from applying to the Court for further or additional relief.

25. **Filing Under Seal.** Any information designated Confidential Information, if filed with the Court in connection with this Action, shall be filed under seal in accordance with the Local Rules or practice of the court in which the information is filed and shall be marked in the caption that the material is being filed under seal by adding the marking "**CONFIDENTIAL – FILED UNDER SEAL**" below each case number appearing in the caption. In addition, any document that is to be filed with the Court and that contains or discloses Confidential

Information shall be marked “**CONFIDENTIAL – FILED UNDER SEAL**” on its cover page. Material designated Confidential and filed under seal shall be maintained in such manner as provided for by the Court. However, the burden of proving that such document should be sealed shall at all times remain on the party that designated the document Confidential.

26. **Challenging Designations.** The acceptance or receipt by any party of material designated Confidential shall not constitute an admission or concession, or permit an inference that such material is, in fact, Confidential. Any Receiving Party may at any time request that the designating party cancel or modify the confidentiality designation with respect to any document, object, or information. Such request shall be made to counsel for the designating party in writing, and shall particularly identify the designated Confidential Information that the Receiving Party contends is not confidential or not Confidential, and the reasons supporting its contention. If the designating party does not agree to remove the Confidential designation within ten business days after receipt of such a request, then the party contending that such documents or material are not confidential may request by motion that the Court remove such material from the restrictions of this Protective Order in accordance with the procedures set forth in the Court’s Scheduling Order for resolution of discovery disputes. On such a motion, the party asserting confidentiality shall have the burden of proving that the material designated Confidential warrants protection under this Protective Order.

27. **No Expansion of Scope of Discovery.** Nothing in this Protective Order shall be construed to be an implied admission or to affect or govern the scope of discovery in this Action, or to preclude any party from moving the Court for a further order pursuant to Fed. R. Civ. P. 26(c), or any other provision of the Federal Rules of Civil Procedure. Nothing contained in this Protective Order shall be construed to require production or disclosure of any Confidential

Information deemed by counsel for the party possessing such material to be protected from disclosure by the attorney-client privilege or the attorney work-product immunity, or any other privilege or immunity, so long as the withheld materials are identified in the manner required by the Federal Rules of Civil Procedure by the Producing Party. However, this Protective Order shall not prevent the parties from agreeing that certain categories of documents need not be identified, nor shall it prevent one or more parties from seeking relief from the Court if, e.g., identification of individual documents would be unduly burdensome. This Protective Order shall not preclude any party from moving the Court for an order compelling production or disclosure of such material in accordance with the procedures set forth in the Court's Scheduling Order for resolution of discovery disputes.

28. **New Parties to This Action.** In the event additional parties join or are joined in any of these Actions, they shall not have access to information designated Confidential by any other party until (a) the newly joined party or its counsel has executed and, at the request of any party, filed with the Court, its agreement to be fully bound by this Protective Order, or until (b) an alternative protective order is agreed to by all parties and entered by the Court.

29. **Miscellaneous.** This Protective Order shall not be construed to prevent any of the parties, or any Third Party, from applying to the Court for relief or further or additional protective orders, or from agreeing between or among themselves to modifications of this Protective Order, subject to the approval of the Court. The Protective Order shall not preclude the parties from enforcing their rights against any Third Party not associated with the Actions who is believed to be violating their rights.

30. **Other Proceedings.** By entering into this Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that

information may be relevant and subject to disclosure in another case. Any person or party subject to this Order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

31. **Publicly Available Information.** This Protective Order shall not apply to any information of the parties which: (a) the producing or designating party or parties agree(s) should not be designated as Confidential; (b) the producing or designating party or parties agree(s), or the Court rules, is already public knowledge; (c) the producing or designating party or parties agree(s), or the Court rules, has become public knowledge other than as a result of disclosure by the Receiving Party, its employees, or agents in violation of this Protective Order; or (d) the producing or designating party or parties agree(s), or the Court rules, has come or shall come into the Receiving Party's legitimate knowledge or possession independently of the Producing Party under conditions such that its use and/or public disclosure by the Receiving Party would not violate any obligation to a party to any of these Actions. The restrictions and obligations set forth in this Protective Order shall not prohibit discussion of any material designated Confidential with any person who already has or obtains legitimate possession thereof.

32. **Survival of Obligations under Protective Order.** With respect to any information designated Confidential under this Protective Order, the rights and obligations under this Protective Order shall survive the final termination of these Actions to the extent the information in such material is not or does not become known to the public and continues to be binding upon all persons to whom Confidential Information is disclosed hereunder. Upon final termination of this Action, the outside counsel of record for each party may retain (a) one copy

of all deposition transcripts and exhibits thereto, (b) one copy of all trial transcripts and trial exhibits, (c) one copy of all pleadings and exhibits thereto, (d) one copy of all correspondence and exhibits thereto, (e) expert reports, (f) written discovery responses, and (g) any documents, things, copies and samples to the extent they include or reflect the receiving attorney's work product.

Within ninety (90) days after final termination of this Action, including all appeals, however, counsel for the Receiving Party shall (i) assemble and return to the Producing Party all other copies and samples of material designated Confidential; or, alternatively (ii) certify to the Producing Party in writing the destruction thereof. Accordingly, upon final termination of this Action, no one other than the outside counsel of record for each party shall retain any copies or samples of any material designated Confidential. For the avoidance of doubt, this paragraph applies equally to Confidential Information stored electronically, except that a party is not obligated to return or destroy Confidential Information that may be contained on electronic back-up tapes or other archival media, which should be treated in accordance with standard retention policies.

33. **Waiver or Termination of Order.** No part of the restrictions imposed by this Protective Order may be waived or terminated, except by written stipulation executed by counsel of record for each designating party, or by an Order of the Court for good cause shown. The termination of employment of any person with access to any Confidential Information shall not relieve such person from the obligation of maintaining the confidentiality of such information in accordance with this Protective Order.

34. **Modification of Order; Prior Agreements.** This Protective Order may be modified, and any matter related to it may be resolved, by written stipulation of the parties

without further Order of the Court. This Protective Order supersedes any agreements between the parties regarding the confidentiality of particular information entered into before the date of this Protective Order.

35. **Section Captions.** The title captions for each section of this Protective Order are for convenience only and are not intended to affect or alter the text of the sections or the substance of the Order.

36. **Days.** All references to “days” in this Order shall be construed as calendar days, unless otherwise specifically indicated.

37. **Order Applicable Upon Filing with the Court.** Upon filing this Protective Order with the Court, the Parties agree to treat it as “So Ordered,” subject to any future modifications by agreement of the Parties or by the Court.

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SO ORDERED this 9th day of December, 2019.



United States District Judge

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE: PALBOCICLIB PATENT
LITIGATION

)
) MDL No. 19-2912 (CFC)
)
)

PFIZER INC., WARNER-LAMBERT
COMPANY LLC, PF PRISM C.V., PFIZER
MANUFACTURING HOLDINGS LLC,
PFIZER PFE IRELAND
PHARMACEUTICALS HOLDING 1 B.V.,
and PF PRISM IMB B.V.

Plaintiffs,

v.

)
) C.A. No. 19-743 (CFC) (Consolidated)
)
)

AIZANT DRUG RESEARCH SOLUTIONS
PVT. LTD.,

Defendant.

PFIZER INC., WARNER-LAMBERT
COMPANY LLC, PF PRISM C.V., PFIZER
MANUFACTURING HOLDINGS LLC,
PFIZER PFE IRELAND
PHARMACEUTICALS HOLDING 1 B.V.,
and PF PRISM IMB B.V.,

Plaintiffs,

v.

)
) C.A. No. 19-1863 (CFC)
)
)

MYLAN PHARMACEUTICALS, INC.

Defendant

DECLARATION AND PROTECTIVE ORDER UNDERTAKING

I certify that I have received and carefully read the Stipulated Protective Order ("Order") in the above-captioned Actions and that I fully understand the terms of the Order. I recognize that I am bound by the terms of the Order, and I agree to comply with those terms. I hereby consent to the personal jurisdiction of the United States District Court for the District of Delaware for any proceedings involving the enforcement of the Order. I declare under penalty of perjury under the laws of the United States of America that this Declaration and Confidentiality Undertaking is true and correct.

EXECUTED this ____ day of _____, _____.

Name

Signature

Present Employer or Other Business Affiliation

Business Address